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Attorney Docket No.: 26569U
Date: 5 July 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GOLDMANN

Art Unit: 1712

Examiner: Unknown

Application No.: 10/521,455

Filed: 14 January 2005

Title: **IMPLANT WITH ANTIBIOTIC LONG-TERM ACTION**

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

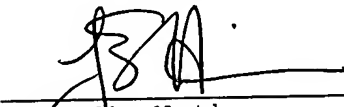
Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- 1) Submission of Documents to Supplement Filing Documents under 35 USC 371;
- 2) PCT/IB/373 (International Preliminary Report on Patentability);
- 3) PCT/ISA/237 (Written Opinion of the International Searching Authority).

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account Number 14-0112.

Respectfully submitted,
NATH & ASSOCIATES PLLC

By:



Gary M. Nath
Reg. No.: 26,965
Tanya E. Harkins
Reg. No.: 52,993
Customer No.: 20529

GMN/TH/le



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SUBMISSION OF DOCUMENTS
TO SUPPLEMENT FILING DOCUMENTS UNDER 35 USC 371

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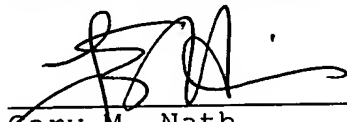
In order to supplement the filing documents for the national phase filing Under USC 371 commenced on **14 JANUARY 2005**, applicant now submits the following documents:

- 1) PCT/IB/373 (International Preliminary Report on Patentability);
- 2) PCT/ISA/237 (Written Opinion of the International Searching Authority).

Please charge any deficiency or credit any overpayment to our Deposit Account Number 14-0112.

Respectfully submitted,
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Reg. No.: 26,965
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference P 43 018 WO	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2004/005162	International filing date (<i>day/month/year</i>) 14 May 2004 (14.05.2004)	Priority date (<i>day/month/year</i>) 15 May 2003 (15.05.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant AESCULAP AG & CO. KG		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
2. This REPORT consists of a total of 8 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input checked="" type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 24 April 2006 (24.04.2006) Authorized officer <p style="text-align: center; font-weight: bold;">Agnes Wittmann-Regis</p> Telephone No. +41 22 338 89 70
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PATENT COOPERATION TREATY

Translation

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference P 43 018 WO		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/EP2004/005162	International filing date (day/month/year) 14.05.2004	Priority date (day/month/year) 15.05.2003
International Patent Classification (IPC) or both national classification and IPC 		
Applicant AESCULAP AG & CO. KG		

1 This opinion contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the opinion
<input checked="" type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

2 FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2004/005162

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2004/005162

Box No. II

Priority

1. ☒ The following document has not yet been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date in the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2004/005162

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-17	YES
	Claims		NO
Inventive step (IS)	Claims	1-17	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims		NO

2. Citations and explanations:

1. Reference is made in the present report to the following documents:

D1: US 6 530 951 B1 (BATES BRIAN L ET AL) 11 March 2003 (2003-03-11)

D2: DE 32 28 849 A (FRAUNHOFER GES FORSCHUNG) 9 February 1984 (1984-02-09)

D3: US 2003/050689 A1 (MATSON LOUIS R) 13 March 2003 (2003-03-13)

2 INDEPENDENT CLAIM 1

2.1 The technical features of claim 1 are disclosed by none of the cited documents. **Claim 1** and the dependent **claims 2-16** are therefore novel within the meaning of PCT Article 32(2).

2.2 The present application meets the requirements of PCT Article 33(1) because the subject matter of **claim 1** involves an inventive step within the meaning of PCT Article 33(3).

2.2.1 Document D3 is regarded as being the closest prior art to the subject matter of claim 1. It

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2004/005162

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

discloses a coating for medical articles, comprising a polymer (e.g. gelatine, cellulose) and an oligodynamic metal such as silver. Through the continuous release of the oligodynamic ions, the coating generates antimicrobial activity in the vicinity of the article.

2.2.2 The subject matter of claim 1 therefore differs from that known from D1 by virtue of the fact that the silver is located below and not in a layer of an absorbable material. A technical effect has been demonstrated in the present application for this altered layering, the said effect consisting in an improved silver release profile.

2.2.3 The problem addressed by the present invention can therefore be considered that of providing an improved implant with a long-term antibiotic activity by virtue of coating with silver.

2.2.4 The solution proposed in claim 1 of the present application is regarded as being inventive for the following reasons (PCT Article 33(3)):
No prior-art document suggests a silver layer beneath an absorbable polymer layer. The technical effect obtained by this layering was unexpected.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2004/005162

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

Dependent claims 2-16 contain all of the
features of claim 1 and are therefore likewise
inventive within the meaning of PCT Article
33(3).

2.3 **Claims 1-17** meet the requirements of industrial
applicability within the meaning of PCT Article
33(4).

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2004/005162

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

From the description on page 4, lines 1-6 and line 32 to page 5, line 7 it is apparent that the following feature is essential to the definition of the invention:

(1) a sufficiently great layer thickness of at least 1000 Å

Since the independent **claim 1** does not include this feature, it does not meet the requirement of PCT Article 6 in conjunction with PCT Rule 6.3b) that each independent claim must include all of the technical features essential to the definition of the invention.